

X-13199

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Remarks

Claims 1-12 are pending. Claims 4-7 are withdrawn. Claims 1-3, 9, and 11-12 have been canceled.

Claims 8 and 10 have been amended to limit administration to parenteral administration at a dose of 1 ug/kg/day to 10 mg/kg/day. Support for these amendments can be found, for example, at page 12 of the specification.

New claims 13-16 depend from claims 8 and 10. Support for claims 13-16 can be found, for example, at page 12 of the specification. Support for new claims 17-18 can be found, for example, at page 13 of the specification. No new matter has been added by any of these amendments. Applicants request entry.

Rejection of Claims 1-3, 9 and 11 under 35 USC Section 112

Claims 1-3, 9 and 11 were rejected under 35 USC Section 112, first paragraph, allegedly for non-enablement. Without conceding the basis for this rejection, Applicants have canceled these claims while reserving the right to later claims this subject matter thereby rendering the rejection moot. Applicants respectfully request withdrawal of this aspect of the rejection.

Rejection of Claims 1-3, and 12 under 35 USC Section 102(b)

Claims 1-3, and 12 were rejected under 35 USC Section 102(b), allegedly as being anticipated by US Patent Application Publication 2002/0065210 (hereinafter "Ashkenazi"). Without conceding the basis for this aspect of the rejection, Applicants have canceled claims 1-3 and 12 thereby rendering the rejection moot. Applicants reserve the right to later claim this subject matter.

Applicants will address the rejection as to claims 8, 10 and new claims 13-18. Claims 8 and 10 and new claims 13-16, dependent therefrom, are directed at a method for treating chronic obstructive pulmonary disease (claim 10) and pulmonary fibrosis (claim 8) by administering a specific dose of FLINT. Ashkenazi does not disclose either of these aspects of the claimed invention. As such claims 8, 10, and 13-16 are not anticipated by Ashkenazi.

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New claims 17 and 18 are directed at methods for treating pulmonary fibrosis (claim 17) and chronic obstructive pulmonary disease (claim 18) by continuous infusion of FLINT at specific dose ranges. Ashkenazi does not teach each of the elements in these claims. As such Ashkenazi does not anticipate claims 17 and 18. Applicants respectfully request withdrawal of this basis of the rejection and passage of the claims to issuance.

Rejection of Claims 8-9 and 10-11 under 35 USC Section 103

Claims 8-9 were rejected for allegedly being obvious over Ashkenazi in view of Hagimoto et al. (hereinafter "Hagimoto"). Without conceding the basis for this rejection, Applicants have canceled claim 9 thereby rendering the rejection moot as to claim 9.

*Prima facie* obviousness over a combination of references requires motivation to combine the cited references [See e.g. MPEP §706.02(j)]. In this case, even if there were motivation to combine Ashkenazi and Hagimoto, the combined teaching would not suggest Applicants' claimed invention. These references alone or together do not suggest Applicants' claimed invention. In particular there is no suggestion as to the particular disease being treated nor the particular dose or dose range being claimed. As such, claim 8 would not be obvious over Ashkenazi, alone or in combination with Hagimoto.

Applicants will also address the rejection as to new claims 13-18. Neither Ashkenazi nor Hagimoto, alone or taken together, discloses or suggests the specific dose ranges claimed. As such new claims 13-18 would not be obvious over Ashkenazi, alone or in combination with Hagimoto. Applicants request withdrawal of this basis of the rejection.

Claims 10-11 were rejected for alleged obviousness over Ashkenazi in view of Yamamoto et al. (hereinafter "Yamamoto") and Hebestreit et al. (hereinafter "Hebestreit"). Without conceding the basis for this rejection, Applicants have canceled claim 11 thereby rendering the rejection moot as to claim 11.

Even if there were motivation to combine Ashkenazi with

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Yamamoto and Hebestreit, the combined teaching would not suggest Applicants' claimed invention. Taking these references alone or together would not suggest Applicants' claimed invention. In particular there is no suggestion in any of these references as to the particular dose or dose range being claimed. As such, claim 10 would not be obvious over Ashkenazi, alone or in combination with Yamamoto and Hebestreit.

Applicants will also address the rejection as to new claims 13-18. Neither Ashkenazi nor Yamamoto and Hebestreit, alone or taken together, discloses or suggests the specific dose ranges claimed. As such new claims 13-18 would not be obvious over Ashkenazi, alone or in combination with Yamamoto and Hebestreit. Applicants request withdrawal of this basis of the rejection.

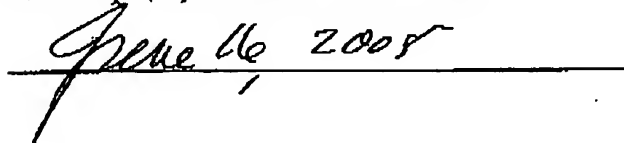
Applicants submit they have successfully addressed each point of the rejection and respectfully request withdrawal of the rejection and passage of the case to issuance as soon as possible.

Respectfully submitted,



Thomas D. Webster  
Attorney/Agent for Applicant(s)  
Registration No. 39,872  
Phone: 317-276-3334

Eli Lilly and Company  
Patent Division  
P.O. Box 6288  
Indianapolis, Indiana 46206-6288



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<b>FEE TRANSMITTAL</b>  effective December 8, 2004				Complete if Known																																																																																					
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1. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to: Deposit Account Number: <b>05-0840</b> Deposit Account Name: <b>Eli Lilly and Company</b> <input checked="" type="checkbox"/> Charge Any Additional Fee Required <input type="checkbox"/> Charge the Issue Fee Set in 37 CFR 1.18 at the time of allowance				3. ADDITIONAL FEES <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Large Entity Fee Code</th> <th>Large Entity Fee (\$)</th> <th>Fee Description</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr> <td>1051</td> <td>130</td> <td>Surcharge-late filing fee or oath</td> <td></td> </tr> <tr> <td>1052</td> <td>50</td> <td>Surcharge-late provisional filing fee or cover sheet</td> <td></td> </tr> <tr> <td>1053</td> <td>130</td> <td>Non-English specification</td> <td></td> </tr> <tr> <td>1251</td> <td>120</td> <td>Extension for reply within first month</td> <td></td> </tr> <tr> <td>1252</td> <td>450</td> <td>Extension for reply within second month</td> <td>450.00</td> </tr> <tr> <td>1253</td> <td>1,020</td> <td>Extension for reply within third month</td> <td></td> </tr> <tr> <td>1254</td> <td>1,590</td> <td>Extension for reply within fourth month</td> <td></td> </tr> <tr> <td>1255</td> <td>2,160</td> <td>Extension for reply within fifth month</td> <td></td> </tr> <tr> <td>1401</td> <td>500</td> <td>Notice of Appeal</td> <td></td> </tr> <tr> <td>1402</td> <td>500</td> <td>Filing a brief in support of an appeal</td> <td></td> </tr> <tr> <td>1452</td> <td>500</td> <td>Petition to revive-unavoidable</td> <td></td> </tr> <tr> <td>1453</td> <td>1,800</td> <td>Petition to revive-unintentional</td> <td></td> </tr> <tr> <td>1502</td> <td>1,400</td> <td>Utility issue fee (or reissue)</td> <td></td> </tr> <tr> <td>122</td> <td>130</td> <td>Petitions to the Commissioner</td> <td></td> </tr> <tr> <td>1801</td> <td>790</td> <td>Request for Continued Examination (RCE)</td> <td></td> </tr> <tr> <td colspan="3">other fee (specify)</td> <td></td> </tr> <tr> <td colspan="3">other fee (specify)</td> <td></td> </tr> <tr> <td colspan="3">other fee (specify)</td> <td></td> </tr> <tr> <td colspan="3">other fee (specify)</td> <td></td> </tr> <tr> <td colspan="3">SUBTOTAL (3)</td> <td>(\$ )450</td> </tr> </tbody> </table>		Large Entity Fee Code	Large Entity Fee (\$)	Fee Description	Fee Paid	1051	130	Surcharge-late filing fee or oath		1052	50	Surcharge-late provisional filing fee or cover sheet		1053	130	Non-English specification		1251	120	Extension for reply within first month		1252	450	Extension for reply within second month	450.00	1253	1,020	Extension for reply within third month		1254	1,590	Extension for reply within fourth month		1255	2,160	Extension for reply within fifth month		1401	500	Notice of Appeal		1402	500	Filing a brief in support of an appeal		1452	500	Petition to revive-unavoidable		1453	1,800	Petition to revive-unintentional		1502	1,400	Utility issue fee (or reissue)		122	130	Petitions to the Commissioner		1801	790	Request for Continued Examination (RCE)		other fee (specify)				other fee (specify)				other fee (specify)				other fee (specify)				SUBTOTAL (3)			(\$ )450
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